510(k) SUMMARY K013003

SUBMITTED BY
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April 15, 2002

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME
Common/Usual Name: Sterilizable Instrument Tray and Accessories
Product Classification: Class II
Proprietary Name: APTIMAX™ Instrument Tray, Instrument Tray Holder and Instrument Tray Mat

PREDICATE DEVICES
The predicate devices are the APTIMAX™ Instrument Tray for use in the STERRAD® Sterilization System, currently manufactured and distributed by Advanced Sterilization Products, the STERRAD® Instrument Tray which is also currently manufactured and distributed by Advanced Sterilization Products and the Instrument Management System manufactured by Hu-Friedy.

INDICATIONS-FOR-USE
The APTIMAX™ Instrument Trays are designed to encase surgical instruments for sterilization in steam, ethylene oxide and STERRAD Sterilization Systems.

DEVICE DESCRIPTION
The APTIMAX™ Instrument Tray, Instrument Tray Mat and Instrument Tray Holder are intended to encase surgical instruments for sterilization in steam (with the exception of gravity displacement cycles), ethylene oxide and STERRAD® Sterilization Systems.

The instrument tray, available in various sizes, is injection molded with a Liquid Crystal Polymer, which is compatible with various sterilization systems such as the STERRAD® Sterilization System, steam sterilizers and ethylene oxide sterilizers.

The tray is designed with a high perforation area on the lid, base and side panels to enhance diffusion of sterilant during sterilization. The hole size and spacing is the same in all trays to enable the use of a common design instrument tray mats and holders.

Prior to sterilization, the tray is over-packaged with a microbial barrier, such as polypropylene CSR wrap or pouch, which is compatible with the sterilization method for maintaining sterility after sterilization.

Accessories for the APTIMAX™ Instrument Tray include the Instrument Tray Holder and the Instrument Tray Mat. The holder and mat are designed to secure and provide protection of delicate endoscopic and microsurgical instruments in the APTIMAX™ Instrument Tray.

The instrument holder and mat, available in various sizes, are manufactured from a silicone material, which is compatible with various sterilization systems such as the STERRAD® Sterilization system, steam sterilizers and ethylene oxide sterilizers.

COMPARISON TO THE PREDICATE DEVICE

The APTIMAX™ Instrument Tray and accessories for use in steam and ethylene oxide sterilization are substantially equivalent to the APTIMAX™ Instrument Tray for use in the STERRAD® Sterilization System, the STERRAD® Instrument Tray and the Instrument Management System. All of these devices are intended to encase instruments for sterilization. In addition, all of these devices have a long-standing, basic design concept. Based on the basic design concept, the use of established well known materials, feature comparisons and results of the validation testing, ASP has demonstrated that these devices are substantially equivalent to existing legally marketed devices.

DISCUSSION OF NONCLINICAL STUDIES

Validation Testing

Overkill method was used to demonstrate cycle lethality.

1) **Efficacy Testing of the APTIMAX™ Instrument Tray, Mat and Holder in Ethylene Oxide Sterilization Cycles**

   Sub-process cycle exposures were performed on the Instrument Tray, Mat and Holder in order to validate the biological effectiveness of a half-cycle Ethylene Oxide gas exposure using Biological Indicator carriers inoculated with *B. globigii* endospores ($>10^6$).

   Following half-cycle exposure, all test samples were tested for the presence of surviving microorganisms and were found to be sterile, demonstrating a 6-log spore reduction after half-cycle exposure.

2) **Efficacy Testing of the APTIMAX™ Instrument Tray and Mat in Prevacuum (wrapped) and Flash (unwrapped) Sterilization Cycles**

Efficacy testing in prevacuum and prevacuum flash sterilization cycles was performed using the APTIMAX Tray and Mat. Stainless steel coupons inoculated with *B. stearothermophilus* endospores ($>10^6$) were placed in the center of stainless steel lumens. The validation was performed at minimum temperature parameters and half cycle exposure with a maximum load.

For 132.2 °C pre-vacuum and flash cycles, lethality was achieved with a 1.5 minute half-cycle in lumen configuration (maximum load and test temperature of 131.7 °C). No growth was observed at half cycle for three consecutive runs for both prevacuum and flash cycles.

3) **Efficacy Testing of the APTIMAX™ Instrument Tray Holder in Prevacuum (wrapped) and Flash (unwrapped) Sterilization Cycles**

Efficacy testing in prevacuum and prevacuum flash sterilization cycles was performed on the Instrument Tray and Holder. Paper spore strip coupons inoculated with *B. stearothermophilus* endospores ($>10^6$) were placed between instruments and the contacting surfaces of the holders. The validation was performed at minimum temperature parameters and half cycle exposure with a maximum load.

For 132.2 °C pre-vacuum and flash cycles, lethality was achieved with a 1.5 minute half-cycle (test temperature of 131.7 °C) for both prevacuum and flash cycles. No growth was observed at half cycle for three consecutive runs.

4) **Efficacy Testing of the APTIMAX™ Instrument Tray, Mat and Holder in the STERRAD 100 Sterilization System**

Efficacy testing was performed on the APTIMAX Instrument Tray, Mats and Holder in the STERRAD 100 Sterilization System. A stainless steel coupon inoculated with *B. stearothermophilus* endospores ($>10^6$) was placed in the middle of a 3 mm x 400 mm stainless steel lumens and between an instrument and the contacting surface of the holder, simulating worst case locations for sterilization.

Complete inactivation of challenge biological indicators was achieved for three consecutive runs at half-cycle with minimum injection volume. The results demonstrated a minimum sterility assurance level (SAL) of 10^{-6}.

5) **Efficacy Testing of the APTIMAX™ Instrument Tray, Mat and Holder in the STERRAD 100S Sterilization System**

Efficacy testing was performed on the APTIMAX Instrument Tray, Mats and Holder in the STERRAD 100S Sterilization System. A stainless steel coupon inoculated with *B. stearothermophilus* endospores ($>10^6$) was placed in the middle of a 3 mm x 400 mm stainless steel lumen and between an instrument and the contacting surface of the holder, simulating worst case locations for sterilization.

Complete inactivation of challenge biological indicators was achieved for three consecutive runs at half-cycle with minimum injection volume. The results demonstrated a minimum sterility assurance level (SAL) of 10^{-6}.

6) **Efficacy Testing of the APTIMAX™ Instrument Tray, Mat and Holder in the STERRAD 50 Sterilization System**
Efficacy testing was performed on the APTIMAX Instrument Tray, Mats and Holder in the STERRAD 50 Sterilization System. A stainless steel coupon inoculated with *B. stearothermophilus* endospores ($>10^6$) was placed in the middle of a 3 mm x 400 mm stainless steel lumen to simulate a worst case location for sterilization.

A glass substrate spore carrier was inoculated with *B. stearothermophilus* endospores ($>10^6$). It was placed between an instrument and the contacting surface of the holder, simulating a worst case location for sterilization.

Complete inactivation of challenge biological indicators was achieved for three consecutive runs at half-cycle with minimum injection volume. The results demonstrated a minimum sterility assurance level (SAL) of 10^{-6}.

Material Compatibility Studies

1) **Residual Testing of the APTIMAX™ Instrument Tray, Mat and Holder Following Ethylene Oxide Sterilization**
Following full-cycle exposure, tensile bars (representative of tray and mat/holder material) were tested for Ethylene Oxide, Ethylene Chlorohydrin and Ethylene Glycol residuals. Residual results were far below limits proposed in the Federal Register of June 23, 1978.

2) **Material Compatibility of the APTIMAX™ Instrument Tray, Mat and Holder with Steam Sterilization Processing**
This study was designed to simulate the possible material degradation in hospital processing conditions for steam sterilization of trays and accessories over multiple cycles. The 180 mm x 75 mm x 30 mm Instrument Tray was chosen as the sample for this study because it has the smallest physical size as well as the thinnest wall thickness, therefore, it represents the worst case scenario for chemical stress cracking. Tensile bars (fabricated from the same raw materials used for the mat and holder) were used in order to test for tensile strength, indicating bulk phase material degradation. The mats and holders are included in this study so the effect of steam sterilization on design configuration could be evaluated.

The cycle chosen was a gravity-displacement steam sterilization cycle set at a temperature of 270°F with an exposure time of 15 minutes. This cycle condition was chosen to represent the high temperature range cycle of the longest duration time within the cycle.

The trays are loaded with approximately .25 lb. of weight to simulate the heaviest loading of microsurgical instruments.

After processing all of the samples in fifty steam cycles, no change in surface characteristics was observed. The physical properties, represented by tensile strength, had changes within the acceptable limit.

It is therefore concluded that the APTIMAX™ Instrument Tray, Mat and Holder are compatible with steam sterilization processes.

3) **Material Compatibility of the APTIMAX™ Instrument Tray, Mat and Holder in the STERRAD 100 Sterilization System**

The purpose of this study was to simulate possible material degradation of the APTIMAX Trays, Mats and Holders over multiple cycles of STERRAD Sterilization processing. The STERRAD 100 cycle was chosen to represent a typical cycle of all STERRAD Systems. It was chosen due to the fact that materials processed by the STERRAD 50 and the STERRAD 100S generally have less hydrogen peroxide residual than the materials processed in the STERRAD 100. Therefore, the compatibility of most materials processed in the STERRAD 50 and STERRAD 100S are expected to be equal to or better than the STERRAD 100.

After processing the APTIMAX Trays and Tensile bars (representative of tray and mat/holder material) in one hundred full cycles, no change in surface characteristics was observed. The physical properties, as represented by tensile strength had changes within the acceptable limit (<10%) for the trays. All but one of the tensile bars were within acceptable limits. The one that was over the acceptable limit was an one-hundred cycle sample. The tensile bar was tested for hardness change and the results indicated that the change was not significant.

CONCLUSION

Results of validation testing demonstrate that the APTIMAX™ Instrument Tray, Mat and Holder are compatible for use in steam and ethylene oxide sterilization cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Ms. Natalie Bennington
Senior Regulatory Affairs Specialist
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

Re: K013003
Trade/Device Name: APTIMAX™ Instrument Tray and Accessories
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 2, 2002
Received: July 3, 2002

Dear Ms. Bennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

510(k) Number (K013003):

Device Name: APTIMAX™ Instrument Tray and Accessories

Indications-For-Use:

The APTIMAX™ Instrument Trays and accessories are designed to encase surgical instruments for sterilization.

The APTIMAX™ Instrument Trays and accessories were previously indicated for use only with the Sterrad® Sterilization Systems. This Premarket Notification expands the Indications for Use for the APTIMAX™ Instrument Trays and accessories to also include their use in prevacuum steam and ethylene oxide sterilization cycles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Olin S. Lim

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K013003

Prescription Use _____ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)